

VAGIFEM[®]

Oestradiol

CONSUMER MEDICINE INFORMATION

The information in this leaflet is only a summary and is not a complete statement about Vagifem[®]. Your doctor or pharmacist has more detailed information relating to you, your medical history and this medicine and you should consult them if you have any concerns about using Vagifem.

Please read this leaflet carefully before you start to use Vagifem and keep it with your medicine. You may need to read it again.

PRODUCT DESCRIPTION

What is Vagifem[®]?

Vagifem is a modified release pessary used to treat discomfort of the vagina. This is caused by a drop in the level of a hormone called oestrogen. Women have a decreased level of this hormone after menopause. Oestradiol which is in Vagifem is a natural type of oestrogen.

What is in Vagifem[®]?

Each modified release pessary contains 25 micrograms oestradiol (as hemihydrate) which is the active ingredient.

Other ingredients:

Modified release pessaries also contain lactose, maize starch, magnesium stearate, hypromellose and macrogol 6000.

What Vagifem[®] looks like

Vagifem is individually packed as a ready-to-use modified release pessary and applicator for insertion into the vagina. The modified release pessaries are white and round and on one side they are marked 'Novo 279'.

Each box contains 15 single use vaginal applicators.

WHAT VAGIFEM[®] IS USED FOR

Vagifem is used for the treatment of certain vaginal symptoms which occur after menopause, such as dryness, itchiness and pain during sexual intercourse. However, your doctor may prescribe this medicine for another use. If you want more information, ask your doctor.

How Vagifem[®] works

Vagifem when placed in the vagina allows the hormone (oestradiol) to be released. This will increase the moisture of the vagina and relieve or stop discomfort in the vagina. It may take about two weeks for Vagifem to work.

Availability

Vagifem is available only on prescription at pharmacies.

BEFORE YOU USE VAGIFEM[®]

All medicines have benefits and risks. Your doctor has thought about the benefits of you using Vagifem and the risks that may be involved.

You must tell your doctor if:

- you have any unexplained vaginal bleeding
- you have ever had breast cancer or breast lumps
- you know or suspect you have cancer of the lining of your womb
- you know or suspect you have a tumour which depends on hormones
- you have a rare disease of blood pigments (porphyria)
- you suffer from epilepsy
- you suffer from migraine
- you have a known allergy to oestradiol (Vagifem) or any other of the ingredients in Vagifem
- you are pregnant or suspect you are pregnant
- you have diabetes, asthma, heart disease, high blood pressure, blood clots, other blood diseases or liver disease

If any of the conditions mentioned above worsen, treatment with Vagifem should be withdrawn.

Tell your doctor or pharmacist if you are taking other medicines, including any you have bought at your pharmacy, supermarket or health food shop.

The expiry date is marked on the box, for example 08.11.94 refers to the eighth day of the eleventh month of 1994. The medicine should not be used past the expiry date.

Before you start to use Vagifem[®]

- You should have a check-up at your doctors which should include a blood pressure measurement, a gynaecological examination as well as a breast examination.
- See your doctor for regular check-ups.
- Vaginal infections should be treated before Vagifem is used.
- Hormones like oestrogen when given in women after menopause, carry certain risks including some types of cancer.
- Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

USING VAGIFEM®

How to use the medicine

Vagifem should be inserted into the vagina (see diagram at the back of the leaflet). These modified release pessaries are for **vaginal use only and must not be swallowed**.

Dosage

Your doctor will prescribe a dose suitable for you.

When to start: Treatment may start at any suitable time on any convenient day.

When to stop: Your doctor will tell you for how long you should use Vagifem.

Remember it might take up to two weeks for Vagifem to work.

The usual dose of Vagifem is:

Starting dose: 1 modified release pessary daily for two weeks.

After two weeks: 1 modified release pessary twice a week allowing three to four days between doses. eg Monday and Friday.

Practical points: Vagifem treatment should not affect your normal hygiene routine or lifestyle.

Vagifem should not be used in children, males, in pregnancy or during breast-feeding.

Interactions with other medicines

Vagifem contains a very small amount of hormone which should not interact with other medicines you may be using.

If you miss a dose

- Insert Vagifem as soon as you remember.
- Do not use a double dose to make up for the dose that you missed.
- If you have trouble remembering when to use Vagifem, ask your pharmacist for some hints.

Overdose

If you think that you or anyone else may have used too many Vagifem or have accidentally swallowed these modified release pessaries ask your doctor or pharmacist for advice.

WHILE USING VAGIFEM®

Side effects:

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

If while undergoing treatment with Vagifem you experience any side-effects or symptoms which may be due to Vagifem (whether or not it is mentioned below) please inform your doctor or pharmacist as early as possible. You may need medical treatment if you experience some of the side effects. The most common side effects reported are: Mild effects such as slight vaginal bleeding, vaginal discharge, allergic reactions and skin rash. Rarely, other more serious side effects may occur.

Things to be careful of:

Tell your doctor or pharmacist as soon as possible if you do not feel well or have an unwanted side effect while you are using Vagifem. This medicine helps most people with discomfort of the vagina as a result of menopause.

Vagifem is not a contraceptive and will not prevent pregnancy.

Ask your doctor or pharmacist to answer any questions you may have.

AFTER USING VAGIFEM®

Do not give this medicine to anyone else.

Disposal

Return any unused medicine to your pharmacist. Used applicators may be returned to the open blister packs and then discarded carefully.

FURTHER INFORMATION**Storage**

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Vagifem should be protected from light, and stored below 25°C in the manufacturer's original box.

Do not refrigerate.

Other Information

If you have any further questions on your Vagifem treatment, or are unsure of any of the above information, please see your doctor or dispensing pharmacist who will be able to assist you.

Sponsor

Vagifem is made in Denmark for:

Novo Nordisk Pharmaceuticals Pty Ltd

ABN 40 002 879 996

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21 Solent Circuit

Baulkham Hills NSW 2153

Australia

Novo Nordisk Pharmaceuticals Ltd

Auckland, New Zealand

Australian Registration Number

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This leaflet was prepared 18 September 2003

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Australian residents:

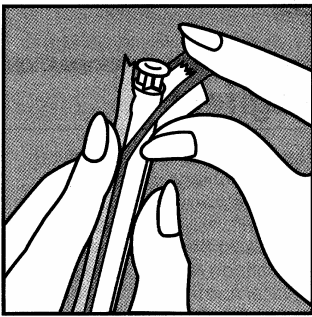
For further information call the NovoCare[®] Customer Care Centre on 1800 668 626.
www.novonordisk.com.au

New Zealand residents:

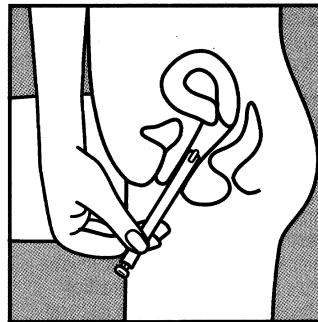
For further information call the NovoCare[®] Customer Care Centre on 0800 733 737.
www.novonordisk.co.nz

HOW TO USE VAGIFEM[®]

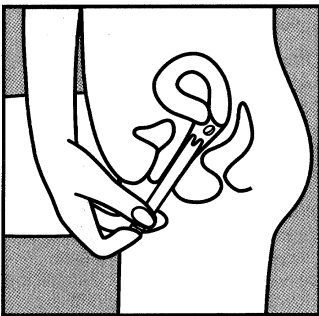
Wash hands well.
Take Vagifem applicator
from its individual
casing.



Get into a relaxed
and comfortable
position. Insert the
applicator, modified release
pessary end first, into your vagina
as far as it will go.



Press the end of the
applicator firmly. You
will feel a click as the
modified release pessary
is released.



Withdraw the applicator
and throw it away.

